K020426

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FEB 2 6 2002

Medtronic Sofamor Danek MSD WIRE System
510(k) Summary

Submitter: Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132

Contact Person: Richard Treharne

Trade Name: MSD WIRE System

Classification Name: Spinal Fixation Orthosis, Class II

Predicate Device(s): The MSD WIRE System is substantially equivalent to itself, the ORFIL Spine Fixation System, which was cleared in K934007 on June 06, 1994.

Device Description: The MSD WIRE System construct consists of rods and segmental sublaminal wiring, being pre-formed and put in place by simple, commonly used, instrumentation. The purpose of this submission is to change the name of the system to the MSD WIRE System and to add previously cleared rods to the MSD WIRE System. The implant components are made of stainless steel as described by ASTM Standard F138 or ISO 5832-1. Stainless steel and titanium implant components must not be used together in a construct.

Intended Use: When properly used, this system will provide temporary stabilization until a solid spinal fusion develops. This system is intended for use only in the thoracic, lumbar and sacral levels of the spine. This system is not for use in the cervical spine. Specific indications include:

1. Degenerative Disc Disease (DDD as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Pseudoarthrosis.
3. Stenosis
4. Spondylolisthesis.
5. Spinal deformities such as scoliosis and lordosis.
6. Fracture.
7. Unsuccessful previous fusion surgery.
8. Tumor resection.

Functionality & Safety Testing: A Risk Analysis was performed on the MSD WIRE System and was included in this submission.

Conclusion: The subject components contained in this submission are substantially equivalent to the original ORFIL Spine Fixation System (K934007).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Richard W. Treharne, Ph.D.
Vice President Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K020426
Trade Name: MSD™ Wire System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: KWP
Dated: February 5, 2002
Received: February 8, 2002

Dear Dr. Treharne:

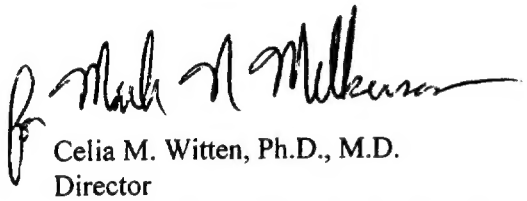
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

February 2002

510(k) Number (if known): K020426

Device Name: MSD WIRE SYSTEM

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Evaluation (ODE)

Prescription Use X OR Over-the-counter Use _____

(Per 21 CFR 801.109)

(Optional 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020426